FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

Meeting of the Gastrointestinal Drugs Advisory Committee(GIDAC)

February 23, 2010

AGENDA

The committee will discuss the efficacy and safety of new drug application (NDA) 22-554 for XIFAXAN (rifaximin) Tablets 550 mg, manufactured by Salix Pharmaceuticals, for the indication (use) of maintenance of remission of hepatic encephalopathy, a condition in which severe liver disease contributes to an accumulation of toxic substances that impair brain function. This indication is for patients 18 years of age and older.

8:00 – 8:10 a.m.	Call to Order Introduction of Committee	AC Chairman
8:10 – 8:15 a.m.	Conflict of Interest Statement	Designated Federal Official, GIDAC
8:15 – 8:30 a.m.	FDA Opening Remarks	Division of Gastroenterology Products
8:30 – 9:30 a.m.	Sponsor Presentation	Salix
9:30 – 10:00 a.m.	Questions to the sponsor	
10:00 – 10:30 a.m.	Break	
10:30 – 11:30 a.m.	FDA Presentation Pre-clinical Toxicology/Clinical	FDA
11:30 – 12 noon	Questions to the FDA	
12:00 – 1:00 p.m.	Lunch	
1:00 – 2:00 p.m.	Open Public Hearing	
2:00 – 5:00 p.m.	Committee Discussion and Questions	
5:00 p.m.	Adjournment	